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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,570	11/09/2005	Sakae Sato	8062-1029	1832

466 7590 04/14/2008

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EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
04/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,570	SATO ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-30* is/are pending in the application.

4a) Of the above claim(s) *28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-27,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/18/05,7/18/05,9/22/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 12-30 are pending. Claims 12-27, 29, 30 are considered on the merits. Claim 28 is withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Claim 28 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 1/29/08.

The traversal is on the ground that the product of claim 28 cannot be produced by any other method. This is not found persuasive because the examiner presented evidence, which has not been factually rebutted, that the product AS CLAIMED is taught by the cited prior art of US 6,867,285. It is of no consequence in a 371 application if the groups are coextensive in scope, if the product is made by the process claims, or whether the groups show one-way or two way distinctness. Applicants allege that the product AS CLAIMED cannot be made by any other method; however, mere allegation that the cited prior art reference does not teach the instant composition is merely that, an allegation unsubstantiated by analysis or objective evidence. The examiner holds that the composition AS CLAIMED is taught by the cited prior art and the requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

On the IDS of 4/18/05, no copies of the cited references are associated with the application.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 12-27, 29, 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites a step of filtering without an object of filtering.

Claims 12 and 13 recite in the preamble that the method is a method of producing a serum product, but the body of the claimed method is directed to plasma.

Claims 13, 25 use the term “immediately” which is a term of reference without a reference point.

Claim 24 recites that blood is passing through steps (a) , (b). However, no blood is seen in the independent claim.

Claims 14, 29, 30 recite "a raw product” or “a raw material” without an antecedent basis in the independent claim.

Claim 26 has no antecedent basis of “virus removal membrane”.

Claim 29 has a square as the last term of the claim.

There are other errors in the form of claims/language. Please clean up the claims in preparation for a possible allowance.

SCOPE of ENABLEMENT

The following is a quotation of the first paragraph of 35 U.S.C. 112:The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 13, 17, 18, 20-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for processing fresh plasma, does not reasonably provide enablement for processing frozen plasma. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The examples are directed to the filter processing of fresh plasma.

Burnouf et al. disclose that processing frozen plasma by the instant method leads to rapid clogging of the filter membrane (page 116, Discussion).

The claims admit the processing of both fresh and frozen plasma.

Undue experimentation would be required to practice the invention as claimed due to the amount of experimentation necessary because of the limited amount of guidance and limited number of working examples in the specification, the nature of the invention, the state of the prior art, breadth of the claims and the unpredictability of the art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-27, 29-30 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Burnouf et al. [U].

Burnouf et al. disclose a method of producing plasma from whole blood by apheresis, leukodepleting the plasma by filtration, nanofiltering the plasma through a Planova-75 and then a Planova-35 filter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-16, 18-26, 29, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 64-051075 [IDS].

The claims are directed to a method for producing a plasma or serum product comprising:

separating plasma from whole blood, reducing leukocytes in the plasma, filtering the plasma with a virus removing membrane.

The reference is relied upon as explained below.

JP 64-051075 discloses a method of treating blood comprising filtering the blood through a leukocyte filter, separating the plasma, passing the plasma through a virus removing membrane.

Although the order of the steps is not the same, i.e. the blood which includes plasma/serum is leukoreduced prior to the separation of red cells, platelets, i.e. producing the plasma, in the absence of evidence of criticality, a change in the order of steps is *prima facie* obvious, see MPEP 2144.04 IV. C.

With regard to the ranges of the size of the pores of the filter, this is considered to be an optimization well within the purview of one of ordinary skill in the art in the absence of evidence to the contrary. See MPEP 2144.05 I.II.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 64-051075 as applied to claims 12-16, 18-26, 29, 30 above, and further in view of JP 3-146067 [IDS].

The claims are further directed to the use of two virus reduction filters of decreasing pore size in tandem.

JP 03-146067 discloses the use of virus removal filter membranes in tandem and in decreasing pore size in order to maintain a high filtration rate.

The substitution of two virus removal membranes with decreasing pore sizes for the single virus removal membrane in the disclosure of JP 64-051075 would have been obvious when taken with JP 03-146067 for the advantages disclosed by JP '067.

Claims 12-16, 18-26, 29, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,190,855 [A] in combination with US 6,861,001 [B] and WO 01/14047 [N].

The claims are directed to a method for producing a plasma or serum product comprising:

separating plasma from whole blood, reducing leukocytes in the plasma, filtering the plasma with a virus removing membrane.

US 6,190,855 discloses a two step method of removing infectious agents from blood constituents. In the summary of invention, and Fig. 7, the first step for treating plasma comprises flowing the plasma through a filter to remove cellular material which may contain viruses, in particular a leukocyte reduction filter. The second step of treating plasma is to remove non-entrained viruses by a chemical agent in a photoactive reaction, thus producing a virus-free plasma.

The reference lacks the teaching of using a membrane filtration step to remove non-entrained viruses.

US 6,861,001 discloses that membrane filtration may be employed to remove viruses from plasma (col. 1, l. 66). Liquids containing cells (e.g. human blood) or other large particles require pre-treatment to separate the cells from

the liquid prior to passing the liquid through the membrane (col. 6, l. 27). The pore size is between 20-1000 nm (col. 2, l. 59).

WO 01/14047 of which US 6,797,169 is an English translation, disclose that filter membranes may be employed for removing viruses from solutions. The solutions may be physiologically active products which are used as raw materials of medicinal products (col. 12, l. 30 of US '169).

The substitution of the membrane filtration step of US 6,861,001 or WO 01/14047 for the chemical viral photo-inactivation step in the two step process of US 6,190,855 would have been obvious because US '001teaches the use of membrane filtration to remove viruses from protein solutions such as plasma, (col. 2, l. 5) and the removal of cells from the liquid prior to filtration (col. 6, l. 35). Also, WO 01/14047 teaches that virus removal using various chemical treatments has been used in the prior art, but that removal of viruses by membrane filtration is also possible (col 1, l. 15 of US '169).

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,190,855, US 6,861,001, WO 01/14047 as applied to claims 12-16, 18-26, 29, 30 above, and further in view of JP 3-146067 [IDS].

The claims are further directed to the use of two virus reduction filters of decreasing pore size in tandem.

JP 03-146067 discloses the use of virus removal filter membranes in tandem and in decreasing pore size in order to maintain a high filtration rate.

The substitution of two virus removal membranes with decreasing pore sizes for the single virus removal membrane in the disclosure of US 6,861,001 or WO 01/14047 would have been obvious when taken with JP 03-146067 for the advantages disclosed by JP '067.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions/additions in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/
Primary Examiner
Art Unit 1651